

Remarks

Claims 1, 2 and 7 – 19 are pending. Claims 17 – 19 are cancelled. Claim 1 is amended only by adopting the suggestions of the examiner with regard to the rejections under Section 112. Correspondingly, no new matter is added by these amendments. The scope of claim 1 is not believed to be narrowed by these amendments in any way that would justify citation of new references in a Final Action, as discussed below.

I. Rejections under Section 112

Claims 1, 2 and 7 - 16 stand rejected under 35 U.S.C. Section 112. The amendments to claim 1 address this rejection. The word "only" objected to by the Examiner, has been removed from the claim. With regard to support for the "claimed means for delivering pacing pulses", it may be found as follows:

As described in paragraph 3, implantable medical devices are available which generate pacing pulses. These devices are in fact widely sold, are typically referred to as "pacemakers" and are familiar to those of skill in the art. As described in paragraph 5, these devices deliver pacing pulses between a bipolar pair of electrodes, one serving as anode, one as cathode. As described in paragraph 27, the bipolar pair of the present invention used for pacing may include electrodes located on two different leads, each lead being coupled to the implantable medical device, (e.g. device 1, Figure 1) which correspondingly is the "means for delivering pacing pulses".

In addition, the term "low voltage", objected to by the Examiner, has been replaced with "pacing". As reflected throughout the specification, the "low voltage" electrodes are pacing electrodes, consistent with common usage in the relevant field. The claims already contain this limitation, as the electrodes are used to deliver pacing pulses. These two terms are used interchangeably not only in the present specification but by the Examiner in the issued Office Actions

in the present case. While the need for this change is respectfully traversed, it is made in the hope it will assist in obtaining a timely allowance of the application.

The claims are believed to be in no way substantively narrowed by the above discussed amendments. As such, it is respectfully asserted that the amendments cannot reasonably be argued to necessitate the citation of new references. It is respectfully asserted that the fact that the claims as submitted were not properly rejected over the references of record is the only plausible reason to cite new art. It is therefore respectfully requested that any new ground of rejection be properly presented in the form of a non-final action.

II. Rejection under Section 103 –Carson in view of Helland

Claims 1, 2, 7 – 10 and 16 stand rejected under 35 U.S.C. Section 103 as being obvious over Carson (US 5,931,862) in view of Helland (US 5,466,254). This rejection is respectfully traversed.

The claims expressly require a system comprising a pacing pulse generator and first and second leads. The Carson reference does not show such a system. This much has at least been acknowledged by the Examiner.

The claims further require that pacing pulses are delivered between two electrodes, one on each lead. The Helland reference is cited as providing this aspect of the invention. To this extent only, Applicants acknowledge that this is so. However, the analysis does not end here.

The claims also require delivery of pacing pulses between the two electrodes on the two leads, occurs between an electrode on one lead that is provided with a porous covering and an electrode on the other lead which is not. Because the rejection is under Section 103, Applicants understand that this fact is not disputed by the Examiner. The question then is whether the references, taken together suggest that this should be done. It is Applicant's contention that they do not do so.

The reason for practicing the invention, as set forth in the present application, is to prevent stimulation of tissue adjacent the covered electrode. There is no assertion by the Examiner that this problem is addressed or even recognized by the Helland reference. Instead, the Examiner takes the position that Carson provides the relevant teaching. The Examiner states:

Carson discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue. However,

Because the rejection is based upon obviousness, it must be set forth with sufficient specificity to show that it does so. The rationale set forth by the Examiner as copied above, to the extent it is understood, defies common sense and is therefore inadequate as a basis for rejection of the claims. See *Perfectt Web Technologies, Inc. V. InfoUSA, Inc.* This opinion is expressly intended to provide standards for obviousness-type rejections and contains much of value to both Examiners and Applicants.

For the following reasons, it is respectfully asserted that the Examiner's rationale does not properly support a rejection under Section 103.

1. The Examiner's rationale is expressly based upon the statement: "The prevention of chronic tissue ingrowth... is a sufficient and effective means of

preventing the electrode from stimulating tissue in proximity of the electrode". This argument directly contradicts the express teaching of Carson and is contrary to common sense. The prevention of fibrotic growth into the covering is specifically disclosed as enhancing the ability of electrode 16, to which the rationale expressly refers, to stimulate tissue in proximity thereto. A copy of Carson's Abstract which is entirely consistent with the rest of the specification, follows below.

A continuous sheath of open-celled porous plastic, preferably ePTFE, is used on the outside of a medical lead, extending along the lead body and the electrodes. Because the plastic is open-celled, when the pores are filled with saline, the lead can deliver electrical energy through the pores in the plastic. Pore size is chosen to discourage tissue ingrowth while allowing for defibrillation energy delivery and electrical signals through it. The porous plastic has a biocompatible wetting agent applied to it to speed the process of filling the pores with saline.

Moreover, the porous layer is also intended to allow stimulation using pacing pulses delivered therethrough. Atrial pacing electrodes 42 and 44 (Figure 3), between which atrial pacing pulses are by definition delivered, are both covered by the same porous coating as electrode 16. If it prevented stimulation of tissue adjacent the electrodes by pacing pulses, the electrodes would serve no purpose.

It is respectfully asserted that the Examiner's interpretation of Carson, on which the rejection under Section 103 relies, is contrary to common sense. As such, the rejection is respectfully asserted to be clearly improper.

More importantly, the problem addressed by the present invention is not recognized or addressed by either of the cited reference. In particular, the invention as claimed addresses the problem of delivering a pacing pulse between electrodes in two different heart chambers while stimulating only a desired one of the two chambers. The relevant teaching of the two references suggests that the solution to this problem would not be that of the present invention, as the porous layer in Carson is to enhance rather than defeat stimulation.

In summary:

1. Neither cited reference recognizes the problem solved by the claimed invention.
2. To the extent they have relevant teaching to the problem, they teach directly away from the claimed invention.
3. The Examiner's interpretation of the Carson reference is contrary to the express teaching of the Carson reference. The rationale for rejection based upon this interpretation thus defies common sense.

Withdrawal of the rejection of claims 1, 2, 7 – 10 and 16 is respectfully requested.

III. Rejections under Section 103 –Carson in view of Helland and Hull or Soukup

Claims 11 - 15 and 16 stand rejected under 35 U.S.C. Section 103 as being obvious over Carson (US 5,931,862) in view of Helland (US 5,466,254) in view of Hull, et al. (US 5,269,810) or Soukup, et al (US 5,466,252). This rejection is respectfully traversed.

These rejections all depend upon the erroneous rejection of claim 1 as discussed above. Withdrawal of these rejections is correspondingly requested.

Conclusion

Applicants respectfully assert that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

The remarks presented herein are believed fully responsive to the Office Action and are believed sufficient to overcome the rejections presented in the Office Action. However, there may be other arguments to be made as to why the

pending claims are patentable. Applicant does not concede any such arguments by having not presented them herein. Finally, please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

/Reed A. Duthler/
Reed A. Duthler
Reg. No. 30, 626
(763) 526-1564
Customer No. 27581